DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 7 1999

Mr. B.J. Hammarback
MRLB International, Incorporated
2450 College Way
Fergus Falls, Minnesota 56537

Re: K992868
Trade Name: DentaPure DP40 Cartridge
Regulatory Class: I
Product Code: EIA
Dated: August 23, 1999
Received: August 26, 1999

Dear Mr. Hammarback:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will

verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K992868

Indications for Use Statement

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Applicant: MRLB International, Inc.

510(k) Number (if known):

Device Name: DentaPure DP40 Waterline Purification Cartridge

Indications For Use:

The DentaPure® DP40 Cartridge is for use on dental unit water lines attached to the dynamic dental instruments, i.e., high-speed handpiece, three-way air/water syringe and ultrasonic scaler. This cartridge in conjunction with currently recommended practices regarding sterilization and flushing of dental instruments reduces bacteria from the water supplied through the instruments to a level that will meet or exceed the current ADA recommendations for water quality having a maximum of 200 cfu/ml.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992868

Prescription Use ✓
(Per 21 CFR 801.109)

K992868

SEP 7 1999

"510 (K) SUMMARY"
[As required by 807.92(c)]

Submitter:	MRLB INTERNATIONAL, INC. 2450 College Way Fergus Falls, Minnesota 56537
Telephone: Fax: Contact Person:	(218) 739-2222 (218) 736-3241 B. J. Hammarback
Date:	August 8,1999
Trade Name:	DentaPure® DP40 Cartridge
Common Name:	Dental Unit Waterline Purification Cartridge
Classification Name:	Accessory for "Unit, Dental Operative" per CFR 872.6640) Class I.
Equivalent Device:	DentaPure® DP1 (K963548) Manufactured by: MRLB International, Inc. 2450 College Way Fergus Falls, MN 56537 [per 807.92(a) (3)]
Device Description and Intended Use:	The DentaPure® DP40 Cartridge is an in-line assembly incorporating iodinated resin and a polyolefin filter. The cartridge is connected to the pickup tube of a bottle water system. This is illustrated in Figure 1. A schematic of the cartridge is shown in Figure 2. It consists of a polyolefin in-line filter with the inner chamber filled with an iodinated ion exchange resin that imparts 2-6 ppm of iodine into the water as it flows through. The resin is registered with EPA. The

filter portion is of a sufficiently small porosity to retain water-born particulate, and would thereby reduce the amount of particulate that would reach the patient from the dental water system. The iodine that is released reduces biofilm and the chance of cross contamination by introducing the germicide, iodine, into the water system downstream of the filter.

The DentaPure® Cartridge is a disposable unit, retrofittable to all modern dental operatory units with independent bottle water systems. The cartridge is installed in the bottle reservoir tubing with quick connect fittings for ease of change.

The instructions for use of the DentaPure® Cartridge require that the dental instruments be sterilized in conformity with current recommendations for sterilization and flushing. When used in conjunction with these normal practices, the DentaPure® DP40 Cartridges commonly reduce bacteria levels to less than 100 cfu/ml. Current recommendations of the ADA recommend having less than 200 cfu/ml in dental unit water lines, so this device exceeds those recommendations.